LEGISLATIVE SERVICES AGENCY
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FISCAL IMPACT STATEMENT

LS 7359
BILL NUMBER: HB 1315

NOTE PREPARED: Mar 12, 2013
BILL AMENDED: Mar 12, 2013

SUBJECT: Biosimilar Biological Products.

FIRST AUTHOR: Rep. Clere
FIRST SPONSOR: Sen. Patricia Miller

BILL STATUS: CR Adopted - 2nd House

FUNDS AFFECTED: X **GENERAL**
DEDICATED
FEDERAL

IMPACT: State

Summary of Legislation: (Amended) This bill allows a pharmacist to substitute a biosimilar product for a prescribed biological product if certain conditions are met.

The bill requires the Board of Pharmacy to maintain an Internet web site that lists the biosimilar biological products that are determined to be interchangeable.

The bill allows the Board of Pharmacy to adopt rules.

It also provides that a written or electronic prescription for a biological product must comply with the existing prescription form requirements.

The bill requires the Health Finance Commission to study, during the 2013 legislative interim, how Indiana law should address the prescribing and substituting of biosimilar biological products.

Effective Date: July 1, 2013.

Explanation of State Expenditures: The Indiana Professional Licensing Agency (IPLA) reports that the Board of Pharmacy Internet web page requirement can be accomplished within the level of resources currently available to the agency.

(Revised) *Health Finance Commission:* The study would have to be conducted during the 2013 interim. This provision will not have a fiscal impact since a study of the topic can be conducted by the existing Health

Finance Commission and if study of the topic does not result in any meetings of the Commission that would not have occurred anyway.

(Revised) *Background Information - Biosimilar Biological Products:* Current Indiana law provides for the substitution of generic drugs for brand name drugs but does not provide for the substitution of the new biotech drugs defined as biological products. The bill defines biological products, biosimilar products, and interchangeable biosimilar products. The bill allows for the substitution of interchangeable biosimilar products for the biological products by a pharmacist so long as the prescriber is notified of the substitution within five days. Biological products (brand names) are currently sold in the U.S. A few copies or biosimilar products are sold in Europe but these are not yet available within the U.S. The Food and Drug Administration is currently working on rules for introducing biosimilars - defining a process different from that for generic drugs to demonstrate the safety, efficacy, and interchangeability of biosimilar products. Currently, there are no biosimilar interchangeable drugs available on the U.S. market.

Explanation of State Revenues:

Explanation of Local Expenditures:

Explanation of Local Revenues:

State Agencies Affected: IPLA, Board of Pharmacy; LSA.

Local Agencies Affected:

Information Sources: IPLA.

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